

## **REMARKS**

Currently, claims 16, 18-21, 39-43, and 45-48, including independent claim 16, are pending in the present application. In the Office Action, independent claim 16 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2006/0008921 to Daniels, et al. in view of U.S. Patent No. 7,014,816 to Miller, et al. and U.S. Patent No. 5,998,161 to Caillouette, et al.

As discussed in the previous response, Daniels, et al. relates to immunochromatographic test strips in which multiple analytes can be detected simultaneously by using more than one semiconductor nanocrystal as a detectable label, each of which emits at a distinct wavelength (p. 1, ¶ [0002]). The assays of Daniels, et al. include semiconductor nanocrystals that have characteristic spectral emissions that can be tuned to a desired energy by varying particle size, size distribution, and/or compositions (p. 2, ¶ [0016]). The semiconductor nanocrystals of Daniels, et al. are used as detectable labels in flow-type assay devices that utilize a suitable absorbent, porous or capillary possessing material suitable thereto (p. 8, ¶ [0124]). Specifically, the assay of Daniels, et al. includes a capture reagent immobilized within a distinct capture region of a chromatographic medium. The capture reagent comprises a capture ligand capable of selectively binding a detection complex. This detection complex includes a detection ligand bound to a target moiety. Thus, upon binding of the detection complex to the capture ligand in the capture region, an immobilized capture complex is formed. (P. 2, ¶ [0021]-[0026]).

Daniels, et al. fail to disclose certain limitations of the present claims, such as the use of a triarylmethane capable of undergoing a detectable color change upon reaction

with one or more amines. Nevertheless, the Office Action cited Miller, et al. as teaching the detection of amines in a test sample.

Miller, et al., however, is directed to a device for detecting *food spoilage*, such as in red meat, pork, poultry, processed meat, and seafood products. (Col. 3). According to the Office Action, it would have been obvious to the colorimetric agent of Miller, et al. in the device of Daniels, et al. to provide an effective means of detecting amines in a sample, such as a food sample.

However, Daniels, et al. is directed to an immunochromatographic test strip assay that is primarily useful for diagnosing a variety of human conditions and diseases, such as pregnancy (hCG present in urine); Down's syndrome (alpha-fetoprotein and acetylcholinesterase in amniotic fluid); myocardial infarction (cardiac markers such as troponin-T and myoglobin); sexually transmitted diseases including gonorrhea, chlamydia, and syphilis (antigens associated with each organism present in blood and/or semen or vaginal secretions); hepatitis, including HAV, HBV and HCV (viral antigens characteristic of each type of virus present in blood, urine, and other bodily fluids); and HIV (viral antigens present in blood, urine and other bodily fluids). One of ordinary skill in the art would have had no reason whatsoever to look to a technique for detecting *food spoilage* for use in the immunochromatographic test strip of Daniels, et al.

The Office Action responds to this argument by noting that the claims do not specifically define the analytes being detected.<sup>1</sup> Still, in conducting an analysis under §

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<sup>1</sup> Ironically, the Office Action also indicates that dependent claims 43 and 44, which were in fact directed to the specific analyte, were improper because they did not further limit claim 16.

103(a), there must be some rationale reason why one of ordinary skill would have been prompted to combine the teachings of the references to arrive at the claimed invention. In this case, the reason purported in the Office Action is nowhere supported by the teachings of the references. One of ordinary skill in the art would simply have not found it obvious to look to a technique for detecting *food spoilage* for modifying the immunochromatographic test strip of Daniels, et al.

The only basis that the Office Action appears to provide to supports its position of obviousness is that Daniels, et al. and Miller, et al. are "analogous art." Even if true, this only relates to whether the subject matter was considered part of the relevant art at the time of the invention. It has no bearing on whether one of ordinary skill in the art would have found it obvious to make the particular combination needed to achieve the claimed invention. If the law were as the Office Action suggests, it would be "obvious" to combine references in any manner desired so long as they are in the same art. This position is tantamount to a finding that any possible detection agent for any conceivable purpose is "obvious" for use in a detection zone in the test strip of Daniels, et al.

The Office Action responds that "the use of the triarylmethane dyes taught by Caillouette in the device of Daniels constitute only a choice between a finite number of identified, predictable solutions, all with reasonable expectation of success." Of course, once the secondary reference is selected by the Office Action, then it is easy to label the number of solutions as "finite." It is in the selection of the reference, however, where the Office Action errs. Respectfully, the so-called "finite number" of solutions is only achieved by selecting a single reference amongst an infinite number of possibilities

without any rationale basis for doing so. A proper analysis under 35 U.S.C. § 103 simply does not permit such a combination.

Furthermore, the fundamental principle of the assay of Daniels, et al. is that the analyte is heterogeneously separated from the test sample as it flows laterally through the test strip. In Miller, et al., however, detection is accomplished by simply contacting a sample with a polymer matrix saturated with the indicator compound. These detection systems are so vastly different that one of ordinary skill in the art would not have found it obvious to selectively pick-and-choose aspects from each reference in an attempt to achieve the limitations of the present claims.

The Office Action responds that it is "irrelevant how the flow of the sample is different since this is not recited in the claims." Regardless of whether a device or method is claimed, however, the Office Action cannot ignore the inconsistent teachings of references simply because they are not claimed in the exact same manner. Instead, the entire teachings of the references must be considered in an obviousness analysis. Respectfully, the Office Action is once again ignoring the proper standards for conducting an obviousness analysis and relying on a hindsight analysis of the claims, which is not proper under § 103.

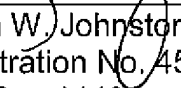
Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Appl. No. 10/790,617  
Amdt. dated Aug. 13, 2009  
Reply to Office Action of May 13, 2009

Please charge any additional fees required by this Amendment to Deposit  
Account No. 04-1403.

Respectfully requested,

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